

# EXHIBIT 3

**IN THE UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF TENNESSEE  
NASHVILLE DIVISION**

PINAL PATEL, Individually, and as Personal )  
Representative of the Estate of GOKULBHAI )  
MAGANBHAI PATEL, Deceased, and on )  
behalf of the Beneficiaries of the Estate, )  
Plaintiff, )

v. )

Case No.  
JURY DEMAND

AMERIDOSE, LLC; MEDICAL SALES )  
MANAGEMENT, INC.; MEDICAL SALES )  
MANAGEMENT SW, INC.; GDC )  
PROPERTIES MANAGEMENT, LLC; ARL )  
BIO PHARMA, INC., D/B/A ANALYTICAL )  
RESEARCH LABORATORIES; BARRY J. )  
CADDEN; GREGORY CONIGLIARO; LISA )  
CONIGLIARO CADDEN; DOUGLAS )  
CONIGLIARO; CARLA CONIGLIARO; )  
GLENN A. CHIN; SAINT THOMAS )  
OUTPATIENT NEUROSURGICAL CENTER, )  
LLC; HOWELL ALLEN CLINIC, A )  
PROFESSIONAL CORPORATION; )  
VAUGHAN A. ALLEN, M.D.; SAINT )  
THOMAS HOSPITAL WEST, f/k/a SAINT )  
THOMAS HOSPITAL; SAINT THOMAS )  
NETWORK; and SAINT THOMAS HEALTH, )

Defendants.

**COMPLAINT AND JURY DEMAND**

NOW COMES Plaintiff, Pinal Patel, individually, and as Personal Representative of the Estate of Gokulbhai Maganbhai Patel, deceased, and on behalf of the beneficiaries of the Estate, by and through undersigned counsel, and for their causes of action file this wrongful death complaint for damages against the above-named Defendants alleging the following:

## INTRODUCTION

1. This lawsuit arises as a result of the widespread outbreak of fungal meningitis over the past year that has affected people in at least 20 states and caused over 60 deaths. Over 750 people have been diagnosed with meningitis, abscesses or other related illnesses.

2. The United States Food and Drug Administration (“FDA”) and the Centers for Disease Control and Prevention (“CDC”) identified fungus present in several separate lots of preservative-free injectable steroids, specifically, methylprednisolone acetate (sometimes referred to as “MPA”) and other drugs, that were compounded and distributed by New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center (“NECC”) as the cause of the fungal meningitis outbreak and the resulting injuries and deaths.

3. Multiple vials of MPA, along with other medications developed at NECC have been recalled but the recall was too late for Decedent Gokulbhai Maganbhai Patel, and for many others who have suffered serious and catastrophic injuries or death.

4. During the period of June 2012 through August 2012, Saint Thomas Outpatient Neurosurgical Center, LLC (“Saint Thomas Neurosurgical”) purchased approximately two thousand five hundred (2,500) 80 mg vials of MPA from NECC and then sold and administered the MPA to patients, including Decedent Gokulbhai Maganbhai Patel.

5. In August and September of 2012, Decedent Gokulbhai Maganbhai Patel received two epidural steroid injections (“ESI”) at Saint Thomas Neurosurgical. During those procedures the anesthesiologist injected MPA into Decedent Gokulbhai Maganbhai Patel’s back.

6. One or more of Decedent Gokulbhai Maganbhai Patel’s ESIs came from contaminated lots of MPA that were purchased from NECC. The contaminated lots were subsequently recalled by NECC.

7. Decedent Gokulbhai Maganbhai Patel's injections of MPA caused his pain, suffering, distress and ultimately, his death.

### **PARTIES**

8. At all times relevant to this action, Decedent, Gokulbhai Maganbhai Patel (hereinafter "Mr. Patel" or "Decedent"), was a citizen and resident of Davidson County, Tennessee, and lived at 315 South Main Street, Goodlettsville, Tennessee 37072, at the time of his death. Defendants are responsible for Mr. Patel's death and the months of conscious pain and suffering he endured before dying. Mr. Patel is survived by his two adult children and three adult grandchildren.

9. Plaintiff Pinal Patel, is and was at all relevant times, a citizen and resident of Davidson County, Tennessee and lives at 315 South Main Street, Goodlettsville, Tennessee 37072. Pinal Patel is the adult grandson of Decedent and has been duly appointed Administrator of the Estate of Gokulbhai Maganbhai Patel by the Seventh Circuit Court of Davidson County, Tennessee. Plaintiff has filed proof of his authority as a Domiciliary Foreign Personal Representative in Suffolk County, Massachusetts Probate and Family Court. Plaintiff Pinal Patel brings this suit as Decedent's grandson and Personal Representative of his estate.

10. Defendant, Ameridose, LLC ("Ameridose"), is a Massachusetts limited liability company organized and domesticated under the laws of the Commonwealth of Massachusetts with a principal place of business at 205 Flanders Road, Westborough, Massachusetts 01581. Ameridose is owned by Defendants, Carla Conigliaro, Barry Cadden, Lisa Cadden, and Gregory Conigliaro. The managers of Ameridose are Defendant, Gregory Conigliaro, and Defendant, Barry Cadden. Ameridose's registered agent is Gregory Conigliaro.

11. Defendant, Medical Sales Management, Inc. ("MSM"), is a Massachusetts corporation organized and domesticated under the laws of the Commonwealth of Massachusetts

with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Defendant, Douglas Conigliaro, is the President of MSM. Defendant, Barry Cadden, is the Treasurer of MSM. Defendant, Gregory Conigliaro, is the Secretary of MSM. MSM's registered agent is Gregory Conigliaro.

12. Defendant, Medical Sales Management SW, Inc. ("MSMSW"), is a Massachusetts corporation organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Defendant, Douglas Conigliaro, is the President and Director; Defendant, Barry Cadden, is the Treasurer and Director; Defendant, Gregory Conigliaro, is the Secretary and Director; and Defendant, Lisa Cadden, is Director. MSMSW's registered agent is Gregory Conigliaro.

13. Defendant, GDC Properties Management, LLC ("GDC"), is a Massachusetts limited liability company organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 701 Waverly Street, Framingham, Massachusetts 01702. GDC's manager and registered agent is Gregory Conigliaro.

14. Defendant, ARL BioPharma, Inc., d/b/a Analytical Research Laboratories ("ARL"), is an Oklahoma corporation organized and domesticated under the laws of the State of Oklahoma with a principal place of business at 840 Research Parkway, Suite 546, Oklahoma City, Oklahoma 73104. Thomas C. Kupiec is the Chief Executive Officer and registered agent of ARL.

15. Defendant, Barry J. Cadden ("Barry Cadden"), is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093 and a citizen and resident of the Commonwealth of Massachusetts. Barry Cadden is the President of New England Compounding

Pharmacy, Inc. d/b/a New England Compounding Center (“NECC”), which is a Massachusetts corporation. At least until October 2012, Barry Cadden was NECC’s licensed Pharmacist Manager of Record, as that term is defined by 247 CMR 2.00, and upon information and belief, compounded MPA at NECC. Barry Cadden was a founder and manager of Ameridose and was involved in Ameridose’s day-to-day operations. Barry Cadden was the Treasurer and Director of MSM and MSMSW.

16. Defendant, Gregory Conigliaro (“Gregory Conigliaro”), is an individual residing at 1 Mountain View Drive, Framingham, Massachusetts 01701 and a citizen and resident of the Commonwealth of Massachusetts. Gregory Conigliaro is a principal owner and the general manager of NECC, as well as NECC’s Treasurer, Secretary, Vice President, registered agent, and one of its Directors. Gregory Conigliaro provided financial advice, oversaw day-to-day operations, and regularly appeared in the NECC facility. Gregory Conigliaro is the founder and a manager of Ameridose and involved in Ameridose’s day-to-day operations. Gregory Conigliaro is Secretary and Director of MSM and MSMSW.

17. Defendant, Lisa Conigliaro Cadden (“Lisa Cadden”), is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093 and a citizen and resident of the Commonwealth of Massachusetts. Lisa Cadden is a board member, Director and, at least until October 2012, a pharmacist at NECC. Lisa Cadden, upon information and belief, compounded drugs and was involved in the day-to-day operations of NECC.

18. Defendant, Douglas Conigliaro (“Douglas Conigliaro”), is an individual residing at 15 Hale Drive, Dedham, Massachusetts 02026 and a citizen and resident of the Commonwealth of Massachusetts. Douglas Conigliaro is the President and Director of MSM and

MSMSW. Douglas Conigliaro, upon information and belief, is involved in the day-to-day operations of NECC, Ameridose, MSM, and MSMSW.

19. Defendant, Carla Conigliaro (“Carla Conigliaro”), is an individual residing at 15 Hale Drive, Dedham, Massachusetts 02026 is a citizen and resident of the Commonwealth of Massachusetts and is a Director of NECC.

20. Defendant, Glenn A. Chin (“Glenn Chin”), is an individual residing at 173 Mechanic Street, Canton, Massachusetts 02021 and is a citizen and resident of the Commonwealth of Massachusetts. At least until October 2012, Glenn Chin was a pharmacist at NECC. Glen Chin, upon information and belief, compounded drugs, including MPA, at NECC.

21. Defendant, Saint Thomas Outpatient Neurosurgical Center, LLC (“Saint Thomas Neurosurgical”), is a Tennessee for-profit limited liability company organized and domesticated under the laws of the State of Tennessee. Saint Thomas Neurosurgical’s principal place of business is located on the 9th floor of the Medical Plaza East office building on the Saint Thomas Hospital campus at 4230 Harding Pike in Nashville, Davidson County, Tennessee 37205. Saint Thomas Neurosurgical’s registered agent for service of process is Gregory B. Lanford, M.D., 2011 Murphy Avenue, Suite 301, Nashville, Tennessee 37203.

22. Defendant, Howell Allen Clinic, a Professional Corporation (“Howell Allen Clinic”), is a Tennessee professional corporation organized and domesticated under the laws of the State of Tennessee with its principal place of business in Nashville, Davidson County, Tennessee. Howell Allen Clinic’s registered agent for service of process is Gregory B. Lanford, M.D., 2011 Murphy Avenue, Suite 301, Nashville, Tennessee 37203.

23. Defendant Vaughan A. Allen, M.D., (“Dr. Allen”) is an individual residing at 1209 Waterstone Blvd, Franklin, Tennessee, 37069 and a citizen and resident of the State of

Tennessee. During all relevant times, Dr. Allen was an employee of the Howell Allen Clinic and Saint Thomas Neurosurgical. Dr. Allen is a medical doctor and practices in the specialty of pain management. Dr. Allen was involved in the day to day operations at Saint Thomas Neurosurgical.

24. Defendant, Saint Thomas West Hospital, is a Tennessee non-profit corporation organized and domesticated under the laws of the State of Tennessee with its principal place of business located on the Saint Thomas West Hospital campus at 4220 Harding Pike in Nashville, Davidson County, Tennessee. Saint Thomas West Hospital was formerly known as Saint Thomas Hospital. Saint Thomas West Hospital's registered agent for service of process is E. Berry Holt III, Suite 800, 102 Woodmont Boulevard, Nashville, Tennessee 37205. Hereinafter, Saint Thomas West Hospital shall be referred to as "Saint Thomas Hospital."

25. At all times while providing treatment to Decedent at Saint Thomas Neurosurgical, the physicians, nurses, staff, and other personnel were agents, apparent agents, employees or representatives of Saint Thomas Hospital and were acting within the course and scope of their employment, agency, or apparent agency with Saint Thomas Hospital.

26. Pursuant to the doctrine of *respondeat superior*, Saint Thomas Hospital is vicariously liable for any negligent acts and omissions of their employees, agents, or representatives committed in the course and scope of their employment or agency while treating Decedent.

27. Defendant, Saint Thomas Network, is a Tennessee non-profit corporation organized and domesticated under the laws of the State of Tennessee with its principal place of business located on the Saint Thomas Hospital campus at 4220 Harding Pike in Nashville,



Davidson County, Tennessee. Saint Thomas Network's registered agent for service of process is E. Berry Holt III, Suite 800, 102 Woodmont Boulevard, Nashville, Tennessee 37205.

28. Defendant Saint Thomas Network was formerly known as Saint Thomas Health Services.

29. Saint Thomas Network is a successor of Saint Thomas Health Services.

30. Saint Thomas Network, as the successor of Saint Thomas Health Services, is a manager of Defendant Saint Thomas Neurosurgical.

31. Saint Thomas Network, as the successor of Saint Thomas Health Services, is an owner and/ or member of Defendant Saint Thomas Neurosurgical.

32. Defendant, Saint Thomas Health, is a Tennessee non-profit corporation organized and domesticated under the laws of the State of Tennessee with its principal place of business in Nashville, Davidson County, Tennessee. Saint Thomas Health's registered agent for service of process is E. Berry Holt III, Suite 800, 102 Woodmont Boulevard, Nashville, Tennessee 37205.

33. Defendant Saint Thomas Health was formerly known as Saint Thomas Health Services.

34. Saint Thomas Health is a successor of Saint Thomas Health Services.

35. Saint Thomas Health, as the successor of Saint Thomas Health Services, is a manager of Defendant Saint Thomas Neurosurgical.

36. Saint Thomas Health, as the successor of Saint Thomas Health Services, is an owner and/or member of Defendant Saint Thomas Neurosurgical. Defendants Saint Thomas Network and Saint Thomas Health are hereinafter referred to collectively as "Saint Thomas."

37. The individuals and entities described in paragraphs 10-20 are sometimes collectively referred to as the "NECC Related Defendants."

38. The individuals and entities described in paragraphs 21 – 36 are sometimes collectively referred to as the “Saint Thomas Entities” or the “Tennessee Defendants”

### **JURISDICTION AND VENUE**

39. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1334(b) because as described herein each claim asserted herein is related to a case under Title 11 of the United States Bankruptcy Code (the “Bankruptcy Code”). Specifically, on December 21, 2012, NECC filed a petition for Bankruptcy protection under Chapter 11 of the Bankruptcy Code. This case is pending in the United States Bankruptcy Court for the District of Massachusetts and is styled as *In re: New England Compounding Pharmacy*, Case No. 12:12-19882 HJB (the “Bankruptcy Proceeding”). The Bankruptcy Court has appointed a bankruptcy trustee to administer the Bankruptcy Estate.

40. Further, as a result of the large number of actions arising from the NECC-related meningitis outbreak, on February 12, 2013, the Judicial Panel on Multidistrict Litigation (MDL No. 2419) issued an order under 28 U.S.C. § 1407 transferring various federal court proceedings to the United States District Court for the District of Massachusetts for coordinated or consolidated pretrial proceedings. The transferred actions are pending in the United States District Court for the District of Massachusetts in the Multidistrict Litigation action styled: *In re: New England Compounding Pharmacy, Inc. Products Liability Litigation*, United States District Court, District of Massachusetts, MDL No. 1 :13-md-2419-FDS (the “MDL Proceeding”). The MDL Proceeding has been assigned to the Honorable F. Dennis Saylor, United States District Judge, for pretrial proceedings and coordination.

41. The Bankruptcy Court has not yet set a deadline for filing of claims against NECC’s estate. Plaintiff will submit a timely claim in the Bankruptcy Proceeding at the appropriate time.

42. NECC has express contractual indemnification obligations to, among others: Barry Cadden, Gregory Conigliaro, Lisa Cadden, Carla Conigliaro, Glenn Chin, GDC, and MSM. On information and belief, some if not all of the aforementioned individuals are insureds under NECC's insurance policies. All aforementioned individuals and entities are NECC Related Defendants as that term is used throughout this Complaint.

43. Adversarial cases seeking damages for the benefit of the Bankruptcy Estate and its unsecured creditors have been filed in the bankruptcy proceeding against each of the NECC Related Defendants.

44. By letter dated October 16, 2012, Saint Thomas Neurosurgical provided NECC with written notice of its intent to assert claims for breach of warranty and other remedies against NECC. In addition, Saint Thomas Neurosurgical and Howell Allen Clinic have actively represented themselves to the Bankruptcy Court for the District of Massachusetts as creditors of NECC who have a stake in NECC's bankruptcy proceeding as a result of Plaintiff's claims and the claims of those similarly situated. Saint Thomas Neurosurgical and Howell Allen Clinic objected to the Trustee's motion to establish a deadline for the filing of claims in the bankruptcy proceeding; they argued that the proposed deadline could prevent them from filing an accurate and comprehensive account of their contribution and indemnity claims against NECC. On July 24, 2013, during oral arguments on another motion filed in the Bankruptcy proceeding, Saint Thomas Neurosurgical and Howell Allen Clinic characterized themselves to the Bankruptcy Court as creditors of NECC's Bankruptcy Estate possessed of indemnity and breach-of-warranty claims. In papers presented in response to that same motion, Saint Thomas Neurosurgical and Howell Allen Clinic insinuated that they intend to seek relief from the automatic stay for the purpose of pursuing indemnity claims against NECC. Whatever contribution, indemnity, and

breach-of-warranty claims Saint Thomas Neurosurgical and Howell Allen Clinic have against NECC are predicated on the contaminated MPA purchased from NECC.

45. By Order dated May 31, 2013, Judge Saylor, in the MDL Proceeding, ruled that the this Court has subject-matter jurisdiction over any cases pending in federal court or state court against entities or individuals "affiliated" with NECC whether or not NECC is named as a defendant. Those NECC affiliated entities and individuals referred to by Judge Saylor in his May 31, 2013 Order include the NECC Related Defendants. Accordingly, this action falls within the ruling of this May 31, 2013 Order and this Court has subject matter jurisdiction over this action.

46. In addition or in the alternative to the bases for jurisdiction already asserted, this Court has subject-matter jurisdiction over all claims against the Tennessee Defendants pursuant to 28 U.S.C. § 1367 in that all such claims are so related to claims in this action within the original jurisdiction of this Court that they form part of the same case or controversy under Article III of the United States Constitution.

47. Venue is proper and appropriate in the United States District Court for the Middle District of Tennessee pursuant to 28 U.S.C. § 1391(b)(2), in that all or a substantial part of the events and actions giving rise to the matters asserted in the Complaint occurred in Davidson County, Tennessee.

48. At all times relevant, the Defendants were engaged in the business of developing, compounding, marketing, distributing, promoting, selecting, purchasing and/or selling or administering either directly and/or indirectly, steroids in the State of Tennessee from which they derived significant and regular income.

49. Defendants are subject to the jurisdiction of this Court in that they are generally present in Tennessee, have transacted business within the State of Tennessee, and acting

individually and/or through their agents and employees have committed tortious actions and omissions in Davidson County, Tennessee that have proximately caused the injuries that are the subject of this lawsuit.

50. The NECC Related Defendants are further subject to the jurisdiction of this Court as a result of contracting to supply goods and things in Tennessee, by conducting or soliciting business in Tennessee, by engaging in a persistent course of conduct in Tennessee, and by deriving substantial revenue from goods used or consumed or services rendered in Tennessee.

## **STATEMENT OF FACTS**

### **Relevant Background**

51. NECC is an entity that has filed for bankruptcy and is protected by the automatic stay provisions of 11 U.S.C. § 362.

52. NECC was a compounding pharmacy that compounded, distributed and/or sold drugs to purchasers throughout the United States, including Tennessee.

53. Upon information and belief, NECC was a privately held company that was owned and controlled by Defendants Barry Cadden, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro and Lisa Cadden.

54. Defendants Ameridose, GDC, MSM and MSMSW were affiliates of NECC at all relevant times.

55. At least until October 2012, Defendant Gregory Conigliaro was involved in co-managing day-to-day operations of NECC, MSM, MSMSW, Ameridose and GDC.

56. At least until October 2012, Defendant Lisa Cadden was a licensed pharmacist who, upon information and belief, compounded medications including MPA at NECC.

57. At least until October 2012, Defendant Glenn Chinn was a licensed pharmacist who, upon information and belief, compounded medications including MPA at NECC.

58. At least until October 2012, Defendant Barry Cadden was a licensed pharmacist. In addition to being NECC's President, Barry Cadden was NECC's licensed Pharmacist Manager of Record. Upon information and belief, Barry Cadden compounded medications including MPA at NECC.

59. "Manager of Record or Pharmacist Manager of Record," as defined by 247 CMR 2.00, "means a Pharmacist, currently registered by the [Massachusetts] Board [of Registration in Pharmacy] pursuant to 247 CMR 6.07, who is responsible for the operation of a pharmacy or pharmacy department in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs."

60. Defendant Ameridose, according to an application signed by Gregory Conigliaro and filed with the Massachusetts Board of Registration in Pharmacy on May 14, 2012, is a "distribution center to entities of common ownership – currently Ameridose and NECC, as well as other Properly Licensed Facilities in the future."

61. Upon information and belief and upon the direction of NECC's principals, on April 11, 2011, Ameridose employee, Michelle Rivers, requested certification for pharmacy technicians employed by NECC for use in an inspection of NECC's facilities by the Massachusetts Board of Registration in Pharmacy.

62. On or about August 24, 2012, Ameridose posted an employment opportunity for Registered Pharmacists to work for NECC in Framingham, Massachusetts. In the posting, potential applicants were told to contact [mlord@medicalesalesmgmt.com](mailto:mlord@medicalesalesmgmt.com). Upon information and belief, there were many other occasions where employees of Ameridose, MSM and/or MSMSW would perform services for NECC at the direction of NECC's principals.

63. Between 2006 and the present, Ameridose and NECC would often share a booth

at conferences and conventions with a single banner listing both company names. During that same time, Ameridose and NECC would hold an annual Christmas party for employees of both companies.

64. MSM and/or MSMSW printed materials for and marketed both NECC's and Ameridose's products, including MPA. One former employee of MSM and/or MSMSW stated: "I didn't think there was any difference [between Ameridose and NECC]."

65. Through September 2012, both NECC and Ameridose used MSM and/or MSMSW for sales and marketing functions. NECC's privacy policy on its website referred to the "Ameridose Privacy Policy." In 2012, NECC salespersons recommended NECC's "sister company," Ameridose, for drug compounds that NECC did not have available.

66. MSM and/or MSMSW shared office space owned by GDC with NECC in Framingham, Massachusetts.

67. Since it was formed as a limited liability company in 2006, Ameridose has been controlled by NECC.

68. Both Ameridose and NECC were controlled by Conigliaro and Cadden family members.

#### **Claims Against the NECC Related Defendants**

69. NECC has a well-known history of adverse events relating to its operation as a Compounding Pharmacy. According to the Majority Memorandum for the November 14, 2012 Oversight and Investigations Subcommittee Hearing, NECC has been the subject of multiple complaints to and investigations by the FDA and the Massachusetts Board of Registration in Pharmacy ("MBP") over the past decade often focusing on unsterile conditions at NECC's facilities. For example, the FDA issued a warning letter to NECC in 2006. The FDA letter details numerous problems at NECC including the sale of compounded drugs without patient-specific

prescriptions, compounding copies of commercially available drugs, selling misbranded compounded drugs, and problems with storage and sterility. That warning letter has been available to the public on the FDA's website for years.

70. Between January 2012 and August 2012, NECC's environmental monitoring program for its compounding facility yielded numerous microbiological isolates (bacteria and mold) within the Clean Room used for the production of MPA. NECC Related Defendants knew or should have known of these findings. NECC Related Defendants failed to investigate those isolates and made no effort to identify those isolates. NECC Related Defendants failed to perform any product assessments for the products made in the Clean Room where the isolates were found. NECC Related Defendants failed to take any corrective actions with regards to the isolates that were found. Despite these findings, NECC Related Defendants continued to compound MPA; and Ameridose, MSM and/or MSMSW continued to distribute marketing materials to customers and potential customers touting the cleanliness of the NECC laboratories.

71. On September 26, 2012 in the wake of dozens of cases of fungal meningitis associated with NECC's injectable steroid MPA, state agents raided the New England Compounding Center's lab in a strip mall on Waverly Street in Framingham, Massachusetts.

72. NECC's few remaining employees were scrubbing the compounding areas with bleach. Despite this last-ditch effort, the "clean" rooms were filthy. A leaky boiler stood in a pool of stagnant, dirty water. The autoclaves used to sterilize the product were discolored, tarnished, and contained visible moisture. The air intake came from vents located about 100 feet from a mattress recycling facility that released copious amounts of dust and other contaminants into the air. The air vents in the "clean" rooms were covered with dirt and white fuzz. The metal



shelf in the “clean” room used to prepare MPA was covered in a reddish-brown, cloudy substance.

73. Investigators determined that NECC’s internal records showed dozens of instances of bacterial and fungal contamination within the NECC facility over at least the past nine months. NECC Related Defendants ignored these test results. NECC Related Defendants never even attempted to get rid of these microbial contaminants.

74. Eighty-three out of 321 observed vials from one of three recalled lots of MPA contained a greenish-black substance visible to the human eye. Seventeen other vials contained a white filamentous material. All 50 out of 50 vials tested confirmed the presence of live microbes (whether fungal or bacterial). The CDC and FDA later confirmed the presence of fungus in unopened vials of NECC’s MPA. This is the same fungus that the CDC confirmed was present in at least 40 fungal meningitis cases.

75. Inspections of NECC’s sister company, Ameridose, revealed similarly deplorable conditions, including countless instances of visible contamination of the hoods and rooms used to prepare drug products, insect infestations, birds flying through areas where purportedly sterile products were packaged and stored, and tubs being used to collect rain water that poured through the chronically leaky roof above the “clean” rooms. Ameridose, like NECC, persistently ignored and failed to investigate at least 53 instances of known microbial contamination. Ameridose also hid adverse events associated with its products, failing to report them to the FDA as required by law and instead classifying these events as “patient responses” or “non-complaints” and taking no action to address them.

76. The CDC determined that three lots of 80 mg/ml MPA produced by NECC between May 21 and September 26, 2012 were contaminated with potentially deadly pathogens.

77. In late September 2012, NECC recalled the following lots of methylprednisolone acetate (MPA) 80 mg/ml that it had compounded and sold: Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012; Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012; and Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013.

78. NECC Related Defendants identified Saint Thomas Neurosurgical in Nashville, Tennessee as one of the healthcare providers that received vials of MPA that were part of the September 2012 recall.

79. On or about October 3, 2012, the Massachusetts Department of Public Health (“DPH”) secured the surrender of NECC’s license to operate as a compounding pharmacy.

80. On October 6, 2012, NECC announced that it was recalling “all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts.”

81. On or about October 8, 2012, at the request of DPH, Barry Cadden and Glenn Chin voluntarily ceased their practice as pharmacists. Lisa Cadden also has voluntarily ceased her practice as a pharmacist. Upon information and belief, none of them have practiced as a pharmacist since voluntarily ceasing their practice.

82. On or about October 22, 2012, the Massachusetts Board of Registration in Pharmacy authorized DPH to request the voluntary permanent surrender of the licenses of Barry Cadden, Glenn Chin, Lisa Cadden and NECC. According to DPH, “[i]f the three pharmacists and NECC do not comply, the Board authorized staff to proceed with permanent revocation.”

83. One of the Massachusetts regulations promulgated by the Massachusetts Board of Registration in Pharmacy pertinent to NECC’s operation as a compounding pharmacy mandated

that “[t]he premises of the pharmacy or pharmacy department shall at all times be kept in a clean and sanitary manner.” 247 CMR 6.02(1).

84. According to its Internet website, “ARL is a dynamic contract research organization providing high quality analytical work and problem solving to the pharmaceutical industry.”

85. According to its Internet website, ARL offers “a full range of laboratory services, both analytical and microbiological” and “strives to collaborate with the compounding pharmacists, by helping them improve the quality of the compounds they prepare through meticulous analysis, data interpretation and troubleshooting.”

86. ARL also states on its Internet website that it follows “USP monographs/general chapters[,]” and that it has a formal Quality Assurance Program in compliance with “USP monographs/general chapters[.]”

87. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states: “Your customers have high expectations of you and your compounding pharmacy. You offer exceptional service and quality preparations that are compounded to exacting specifications. *You should expect nothing less from the testing laboratory you entrust.*” (emphasis in original)

88. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states that ARL’s “[t]esting methods and technologies [are] unparalleled in the market today[.]” (emphasis in original)

89. With respect to its sterility tests, ARL, on its website, stated: “We examine each sterility test for growth at days 2, 3, 7 and 14 and log the result. If a test shows no evidence of

microbial growth in either media over the 14 day incubation period, then it complies with the test for sterility. A preliminary sterility report is available after 72 hours of incubation.”

90. Over the last ten years, ARL has conducted sterility testing on samples of MPA compounded by NECC, including samples from Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013.

91. From May through August 2012, NECC sent several samples of its MPA to ARL for sterility testing. As one example, on or about May 21, 2012, NECC sent to ARL two 5ml vials of MPA from a batch of 6,528 vials that came from Lot 05212012@68, which had been compounded by NECC on May 21, 2012.

92. On May 22, 2012, ARL received and tested the two 5ml vials of MPA that NECC sent to ARL on or about May 21, 2012. ARL sent to NECC a Microbiology Report dated May 25, 2012, which stated that the two vials had been tested on May 22, 2012.

93. ARL’s May 25, 2012 Microbiology Report to NECC stated that the “preliminary” results from the sterility test using test method USP 71 showed that the two 5ml vials of MPA that NECC sent to ARL on or about May 21, 2012, were “sterile.” ARL’s report to NECC further noted that the preliminary results were observed “after approximately 72 hours of incubation.”

94. Pursuant to the protocols of test method USP 71, sterility testing on a batch of more than 6,000 vials of MPA should have been conducted on at least 20 vials from the batch.

95. On or about August 10, 2012, NECC caused one 5ml vial of MPA to be sent to ARL for sterility testing from a batch of several thousand vials that are from Lot #08102012@51, BUD 2/6/2013.

96. The Microbiology Reports issued by ARL to NECC between May and September 2012 concerning the sterility testing of MPA indicated that the sterility tests performed by ARL

were conducted in compliance with USP 71.

97. During the summer of 2012, MSM and/or MSMSW sales representatives, on behalf of NECC and Ameridose, distributed copies of the May 25, 2012, ARL Microbiology Report concerning the testing of the vials of MPA from Lot 05212012@68 to customers and/or potential customers in a packet of marketing materials intended to highlight the safety and sterility of the MPA compounded by NECC.

98. ARL was aware of the risk posed by compounding pharmacies, specifically including the risks posed by NECC's compounding practices.

99. In 2002, ARL found that four samples of a steroid compounded by NECC were contaminated with potentially deadly endotoxins.

100. In 2005, ARL's Chief Executive Officer, Thomas Kupiec, wrote in a published article that "there have been reports of tragedies resulting from a lack of quality control in the compounding pharmacy."

101. In 2007, Mr. Kupiec also recognized the dangers of not testing a sufficient number of samples when he wrote in a published article that "one of the recognized limitations of sterility testing is sample size."

102. In May 2007, the FDA issued a consumer update entitled, "The Special Risks of Pharmacy Compounding[.]" which stated that there had been "more than 200 adverse events involving 71 compounded products since 1990. Some of these instances had devastating repercussions."

103. In 2007, despite being aware of the risks to human health posed by compounding pharmacies, Mr. Kupiec advocated for relaxing the USP Quality Assurance Standards for compounding pharmacies. Noting USP 71's requirements of "a minimum number of articles to

be tested in relation to the number of articles in the batch” and a “14-day quarantine of the drug to await final test results[.]” Mr. Kupiec wrote in a 2007 published article that there should be “separate standards for compounding pharmacies and manufacturers.”

104. While the requirements of USP 71 were not relaxed for compounding pharmacies after Mr. Kupiec’s 2007 published article, ARL allowed compounding pharmacies such as NECC to submit an inadequate number of samples for sterility testing, which practice did not comply with USP 71 requirements.

105. GDC which is an acronym for “Gregory D. Conigliaro” owns the real property and is responsible for maintenance and structural improvements at 685-705 Waverly Street, Framingham, Massachusetts.

106. From 1998 until at least October 2012, GDC leased a portion of the premises at Waverly Street to NECC, MSM and MSMSW.

107. In an on-line posting for a property management position at GDC, which appeared on or before October 25, 2012, GDC stated that it “owns an 88,000 square foot facility on seven acres in downtown Framingham. GDC currently has eight major tenants.” GDC described one of the duties and responsibilities of the GDC property manager as follows: “Ensure all tenants operate their businesses in accordance with facility, local [and] state . . . rules and regulations.”

108. GDC maintained a high degree of control over the premises leased by NECC.

109. Until October 2012, the NECC Related Defendants, compounded, tested, marketed and/or distributed MPA.

110. GDC and Gregory Conigliaro knew that NECC was compounding preservative-free MPA at 697 Waverly Street, and further knew that this medication was injected into humans

and was required to be sterile.

### **NECC and the Risks of Pharmacy Compounding**

111. The serious risks of pharmacy compounding were also the subject of considerable public discussion in the pharmacy community and the medical community before the subject fungal meningitis outbreak. In other words, the risks associated with compounded drugs have been known for years.

112. In 2002, the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. The report concluded that “purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that...follows appropriate measures to ensure that injectable products are free of contamination.”

113. On March 24, 2005, *USA Today* published a front page article with the following headline: “**Safety concerns grow over pharmacy-mixed drugs.**” That article discussed growing concern over the fact that drugs produced in bulk by compounding pharmacies are not FDA approved and are not subject to the same oversight as drugs produced by pharmaceutical companies.

114. In 2006, the FDA conducted a survey of compounded drug products. They collected 36 samples from compounding pharmacies across the United States during unannounced visits. Twelve of the 36 samples (33%) failed analytical testing. The FDA survey concluded “poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths.”

115. In May 2007, the FDA published an article titled “The Special Risks of Pharmacy Compounding.” That article highlighted numerous adverse events involving compounded

products. It also warned of the emergence of large scale compounding operations that were clearly operating outside of the bounds of traditional compounding practice.

116. In 2010, the FDA posted an educational video on YouTube regarding concerns over the quality of compounded drugs.

117. On November 5, 2010, the American Society of Anesthesiologists, the American Society of Health-System Pharmacists (“ASHP”) and other medical societies published a joint report regarding drug shortages. That report included an article written by the ASHP stating as follows:

“Compounding pharmacies have also pursued the production of drugs that are in short supply. Caution is warranted because preparations from these pharmacies may not meet applicable state or federal standards (e.g., United States Pharmacopeia chapter 797 or FDA labeling requirements). The sources of raw materials used by compounding pharmacies have been questioned, and apparent lapses in quality control have resulted in serious patient injury, including death.

. . .

Compounding pharmacies may also present patient risks; several deaths have been associated with improperly sterilized compounded products.”

118. In May 2012, the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy. That report advised that “contamination of compounded sterile preparations has caused outbreaks. Since 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products.”

### **The Fungal Meningitis Outbreak**

119. In September 2012, health officials identified an outbreak of fungal meningitis. Investigators traced the outbreak to MPA compounded by NECC.

120. On September 18, 2012, a Vanderbilt University Medical Center clinician notified the Tennessee Department of Health of a patient with fungal meningitis who had received a series of Epidural Steroid Injections (“ESI”) at Saint Thomas Neurosurgical. On that same date,



Dr. Marion Kainer of the Tennessee Department of Health, contacted Saint Thomas Hospital and spoke with the hospital's Infection Preventionist, Candace Smith.

121. Dr. Kainer told personnel at Saint Thomas Hospital that a sentinel event of concern had occurred in a patient who received Epidural Steroid Injections (ESI) at Saint Thomas Neurosurgical. She requested information from the hospital about the procedure, and she requested that the hospital commence an inspection of the Saint Thomas Neurosurgical clinic. She explained that the event required careful investigation, and she requested that the hospital watch for additional potential cases.

122. Two days later, on September 20, 2012, Saint Thomas Hospital reported to the Tennessee Department of Health ("TDH") that two additional patients with meningitis and high levels of white blood cells of unknown cause were reported to the hospital. Both of those patients had likewise received ESIs at Saint Thomas Neurosurgical. Saint Thomas Hospital also reported that MPA used in the ESIs was obtained from NECC.

123. On September 20, 2012, Saint Thomas Neurosurgical closed voluntarily, sequestered its supplies and ordered new supplies from other distributors.

124. According to the CDC, fungal meningitis occurs when the protective membranes covering the brain and spinal cord are infected with a fungus. Fungal meningitis is rare and usually caused by the spread of a fungus through blood to the spinal cord. Fungal meningitis is not transmitted from person to person.

125. According to the CDC, symptoms of meningitis include the following: new or worsening headache; fever; sensitivity to light; stiff neck; new weakness or numbness in any part of the body; slurred speech; and increased pain, redness or swelling at the injection site. Death may result from meningitis.

126. According to the CDC, symptoms of fungal meningitis are similar to symptoms of other forms of meningitis; however, they often appear more gradually and can be very mild at first. In addition to typical meningitis symptoms, like headache, fever, nausea, and stiffness of the neck, people with fungal meningitis may also experience confusion, and dizziness. Patients might just have one or two of these symptoms.

**Saint Thomas Neurosurgical and Dr. Allen's  
Decision to Purchase MPA from NECC**

127. Defendant Saint Thomas Neurosurgical and Dr. Allen are sometimes collectively referred to as the "Saint Thomas Neurosurgical Defendants."

128. Upon information and belief, Dr. Allen was involved in the day to day operations of Saint Thomas Neurosurgical.

129. Upon information and belief, during all relevant times, Dr. Allen was involved in Saint Thomas Neurosurgical's decision to purchase MPA from NECC.

130. Saint Thomas Neurosurgical, its agents and employees, knew or should have known of the dangers of using compounded drugs and specifically products compounded by NECC. These defendants failed to undertake any appropriate due diligence to ascertain the safety and quality of NECC's products.

131. Instead, the only motivation for Saint Thomas Neurosurgical Defendants to purchase steroids in bulk from NECC was price.

132. Saint Thomas Neurosurgical Defendants made the decision to purchase MPA in bulk from NECC was because it was the cheapest steroid.

133. Saint Thomas Neurosurgical Defendants did not conduct appropriate due diligence or investigation into NECC before deciding to purchase and administer NECC

compounded steroids to their patients. The Saint Thomas Neurosurgical Defendants placed their own profits over patient safety.

134. NECC was not authorized to compound and sell MPA in bulk to Saint Thomas Neurosurgical.

135. NECC was only allowed to fill individual prescriptions for individual patients written by appropriately licensed healthcare providers.

136. Saint Thomas Neurosurgical did not use patient-specific individual prescriptions when buying MPA from NECC in bulk.

137. Saint Thomas Neurosurgical could have purchased MPA for use in ESI's from a compounder other than NECC.

138. Saint Thomas Neurosurgical could have purchased MPA for use in ESI's from a pharmaceutical manufacturer, e.g. Pfizer.

139. From 2000 to the present, the medication formulary for Saint Thomas Neurosurgical lists those steroids acceptable for use at Saint Thomas Neurosurgical and includes: Decadron, Depo-medrol, Solumedrol and Celestone Soluspan.

140. The Saint Thomas Neurosurgical formulary does not include generic MPA or MPA from a compounding company.

141. The Saint Thomas Neurosurgical formulary does include, approve and allow for the administration of MPA manufactured by Pfizer under the name Depo-medrol.

142. In late 2010, Saint Thomas Neurosurgical began purchasing MPA from Clint Pharmaceuticals.

143. Clint Pharmaceuticals represents that it has historically recommended that practitioners not use compounded steroids especially when FDA approved products are

available. Saint Thomas Neurosurgical purchased MPA from Clint Pharmaceuticals at the rate of \$6.49 per 80mg/vial.

144. In May 2011, an NECC sales representative emailed Saint Thomas Neurosurgical's facility director, asking what price NECC would need to offer for MPA in order to gain Saint Thomas Neurosurgical's business. The director replied that if NECC could get the price under \$6.50 per vial she would be willing to "talk" to NECC.

145. On June 9, 2011, Clint Pharmaceuticals increased the price for MPA to Saint Thomas Neurosurgical from \$6.49 to \$8.95 per vial, an increase of \$2.46 per vial.

146. Saint Thomas Neurosurgical was not willing to pay \$8.95 per vial of MPA from Clint Pharmaceuticals.

147. On June 10, 2011, Saint Thomas Neurosurgical emailed an NECC sales representative indicating that if NECC would guarantee a price for MPA of \$6.50 per 80mg vial, Saint Thomas Neurosurgical would be willing to do business with NECC.

148. After NECC indicated its willingness to sell Saint Thomas Neurosurgical MPA for \$6.50 per 1mL 80mg vial, Saint Thomas began ordering from NECC.

149. Saint Thomas Neurosurgical placed its first order with NECC on or about June 10, 2011. That order consisted of 500 80 mg/1mL vials of MPA and 200 80 mg/2mL vials of MPA.

150. The June 2011 order form did not contain any patient names despite the fact that the order form included a column for that information.

151. NECC sent invoices to Saint Thomas Neurosurgical evidencing five separate purchases by Saint Thomas Neurosurgical of five-hundred 80 mg/vials of MPA as reflected in

invoices dated June 6, 2012, June 26, 2012, July 25, 2012, August 13, 2012 and August 31, 2012.

152. NECC charged Saint Thomas Neurosurgical \$6.50 for each 80 mg/vial of MPA.

153. In early to mid-2012, an NECC representative informed Saint Thomas Neurosurgical that NECC needed Saint Thomas Neurosurgical to submit a list of patients with each order in order to comply with Massachusetts Board of Pharmacy rules.

154. The NECC representative was told that Saint Thomas Neurosurgical could not predict which patients would receive MPA. The NECC representative indicated that any list of patient names would suffice.

155. Saint Thomas Neurosurgical provided NECC with a list of previous patients' names (including Mickey Mouse) with their orders for MPA from NECC.

**Decedent is Injected with MPA from NECC and Develops Symptoms of Meningitis**

156. On or about August 15, 2012, Decedent consulted Dr. Allen at Howell Allen Clinic in Nashville, Tennessee, for pain he was experiencing in his back and difficulty walking. Dr. Allen recommended that Mr. Patel undergo two epidural steroid injections, and prescribed the injections accordingly.

157. Mr. Patel underwent the epidural steroid injections on August 27, 2012 and September 10, 2012 at St. Thomas Outpatient Neurological Center, in Nashville, Tennessee.

158. On August 27, 2012, Mr. Patel was administered an injection of 80 mg of MPA compounded by NECC.

159. On September 10, 2012, Mr. Patel was administered an injection of 120 mg of MPA compounded by NECC.

160. Unknown to Mr. Patel, the MPA that was injected into his spine on or about August 27, 2012 and September 10, 2012 was contaminated with a fungus. The lot that

contained the vials of MPA administered to Mr. Patel was recalled after it had been injected into his body.

161. Soon after his MPA injections, Mr. Patel became ill and was hospitalized for two days after the September 10, 2012 injection. He was discharged, but continued to deteriorate, experiencing nausea and vomiting.

162. On October 17, 2012, Mr. Patel was admitted to St. Thomas Hospital with chills, fever, dizziness and weakness, along with lower extremity pain. He was diagnosed with “fungal meningitis after steroid injections.”

163. Mr. Patel died on January 22, 2013 after a long battle with fungal meningitis.

164. From the onset of Mr. Patel’s illness to his death, he experienced extreme conscious physical pain and mental suffering. He died as a result of Defendants’ grossly negligent misconduct, acts and omissions.

165. As a direct and proximate result of the contaminated epidural steroid injections, Mr. Patel contracted fungal meningitis, became very ill, and died

## **CAUSES OF ACTION**

### **COUNT I**

#### **NEGLIGENCE**

#### **(Against NECC Related Defendants)**

166. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

167. As the designer, tester, compounder, seller, marketer and/or distributor of consumer products, the NECC Related Defendants owed a duty to Decedent to comply with existing standards of care, and to exercise due care in providing a safe and quality product.

168. Specifically, but without limitation:

- a. NECC Related Defendants, Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin, owed Plaintiff a duty to provide MPA that was safe and free of contamination.
- b. ARL owed Decedent a duty to properly conduct tests to insure that the MPA was safe and free of contamination.

169. NECC Related Defendants breached those duties, and were otherwise negligent in their design, compounding, sale, testing, marketing and distribution of the recalled steroid medication, which was administered to the Decedent. The Defendants failed to exercise due care in accordance with the standard of care and skill required of, and ordinarily exercised by, a designer, compounder, tester, seller, marketer and distributor of steroid medications as licensed to do so by the Commonwealth of Massachusetts. The Defendants, by and through its supervisors, staff and agents engaged in designing, compounding, storing, testing, selling, marketing and distributing MPA in a negligent manner.

170. NECC Related Defendants further breached those duties by failing to hold the components of the recalled medications; by failing to properly design, compound, test and distribute MPA so that it would not be contaminated with fungus; by failing to properly maintain its facilities where it compounded its medications in a clean, sanitary manner; by failing to oversee the security and quality control of its compounding and distribution facilities; and by allowing contaminated and unsafe compounded medications to reach the stream of commerce for use by Decedent.

171. NECC Related Defendants breached the duties owed to Decedent by failing to use reasonable care in designing, compounding, testing, marketing, distributing and/or selling methylprednisolone acetate.

172. The negligence of NECC Related Defendants was a proximate cause of Decedent's injuries and ultimate death.

173. Plaintiff was caused to be exposed to fungal meningitis through NECC's contaminated steroid that was injected into him in August and September 2012.

174. As a direct and proximate result of the negligence of these Defendants and being injected with contaminated doses of MPA, Plaintiff and Decedent have suffered injuries and death, and damages including but not limited to pain and suffering, emotional distress, anxiety, emotional damage and has incurred medical and other expenses.

**COUNT II**  
**NEGLIGENCE PER SE**  
**(Against NECC Related Defendants)**

175. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

176. NECC Related Defendants owed Decedent a duty to maintain the premises of the pharmacy "in a clean and sanitary manner[.]" 247 CMR 6.02(1), and free from contamination.

177. NECC Related Defendants breached the duties owed to Decedent by failing to use reasonable care in maintaining the premises of the pharmacy "in a clean and sanitary manner[.]" 247 CMR 6.02(1), and free from contamination.

178. NECC Related Defendants also violated Massachusetts' laws and its pharmacy licensing obligations.

179. As a direct and proximate result of the negligence of the Defendants, and being injected with contaminated doses of MPA, Decedent and Plaintiff have suffered injuries and damages as described with particularity, above.

**COUNT III**  
**NEGLIGENT SUPERVISION**  
**(Against NECC Related Defendants)**

180. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:



181. NECC Related Defendants had an obligation and duty to exercise due care, and comply with the then existing standard of care to investigate and hire professional and competent employees to create, test, package, market and distribute the compounded medications, to maintain the facility and its premises, and to make sure the compounded drugs did not create any harm or risk to the Decedent and others who received the compounded medication.

182. In breach of those duties, Defendants failed to exercise due care and failed to supervise their employee(s) or agent(s) who were at all times, working within the scope of their employment and authority. Specifically, and without limitation:

- a. Defendants failed to monitor and test the steroid medication and were otherwise negligent in the supervision of their employees.
- b. Defendants also failed to monitor and supervise the testing of the compounded medications.
- c. The Defendants were negligent in hiring, training, and supervising their employees.

183. The Defendants knew, or should have known, that their employee(s) or agent(s) did not follow proper procedures and knew or should have known of the risks created by failing to do so.

184. As a direct and proximate cause of the breach of those duties, the Defendants permitted the steroid to become contaminated and distributed to patients including the Decedent.

185. As a direct and proximate result of the negligence of the Defendants, and being injected with contaminated doses of MPA, the Decedent and Plaintiff have suffered injuries and damages as described with particularity, above.

**COUNT IV**  
**PUBLIC NUISANCE**  
**(Against Defendants Barry Cadden, Gregory Conigliaro and GDC)**

186. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

187. At all relevant times, Defendants Barry Cadden, Gregory Conigliaro and/or GDC were in control of the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

188. Defendants Barry Cadden, Gregory Conigliaro and GDC owed a duty to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts in a condition that was free from contamination.

189. Defendants Barry Cadden, Gregory Conigliaro and GDC failed to exercise reasonable care in maintaining the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

190. The failure by Defendants Barry Cadden, Gregory Conigliaro and GDC to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts was a proximate cause of the multistate epidemic of fungal meningitis and infections caused by the contaminated MPA.

191. Defendants Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public health and the public safety.

192. Defendants Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public right expressed in 247 CMR 6.02(1).

193. The public nuisance created by Defendants Barry Cadden, Gregory Conigliaro and GDC was a proximate cause of Decedent's injuries.

194. The public nuisance created by Defendants Barry Cadden, Gregory Conigliaro and GDC has caused Decedent special injury in that he sustained injuries to his personal health and ultimately died from said injuries.

195. As a direct and proximate result of the acts and omissions of the Defendants, and being injected with contaminated doses of MPA, Decedent and Plaintiff have suffered injuries and damages as described with particularity, above.

**COUNT V**  
**DECEPTIVE TRADE PRACTICES ACT**  
**(Against NECC Related Defendants)**

196. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, as further and alleges:

197. The MPA injection into Decedent's lumbar spine on August 27, 2012 and/or September 10, 2012 was compounded by NECC.

198. The NECC Related Defendants engaged in trade and commerce within the Commonwealth of Massachusetts.

199. The NECC Related Defendants' negligence, negligent supervision, violation of warranties and nuisance constitutes a violation of the Deceptive Trade Practices Act. The NECC Related Defendants' failure to perform and fulfill its promises, representations, and obligations under the product's warranties, constitutes an actionable violation.

200. As described herein, the NECC Related Defendants represented that their product had characteristics, uses and benefits that it did not have.

201. As describe herein, the NECC Related Defendants represented that their product was of a particular standard, quality and grade that they either knew or should have known was not of the standard, quality or grade described.

202. The NECC Related Defendants failed to provide accurate disclosures of all material information before Decedent and Decedent's providers transacted to use NECC Related Defendants' product.

203. The NECC Related Defendants willfully and knowingly failed to abide by regulations, laws and guidelines set forth to protect consumer safety, including Decedent, constituting a violation of the Act.

204. The NECC Related Defendants' willful and knowledgeable withholding of important safety information and critical product information constitutes a violation of the Act.

205. The NECC Related Defendants actively, knowingly, and deceptively concealed their knowledge of their product's dangerous properties and life-threatening risks. This conduct evidences bad faith and unfair and deceptive practices.

206. The NECC Related Defendants engaged in the conduct as described herein that created a likelihood of confusion and misunderstanding.

207. The NECC Related Defendants engaged in the conduct as described herein that created a likelihood of causing injury to unknowing consumers, including the Decedent.

208. The NECC Related Defendants' conduct as described herein constituted unfair and deceptive acts and practices, including, but not limited to:

- a. Misrepresenting the nature, quality, and characteristics about the product;
- b. Unfairly violating regulations, laws and guidelines set forth to protect consumer safety;
- c. Unfairly exposing unknowing consumers, including the Decedent, to significant, unnecessary risk of harm and actual harm and injury; and

d. All other unfair and deceptive acts set forth herein.

209. The practices described herein are unfair because they offend public policy as established by statutes, the common law, or otherwise. Additionally, the NECC Related Defendants were unethical and unscrupulous, and caused substantial injury to consumers. The NECC Related Defendants engaged in unconscionable actions and courses of action.

210. The NECC Related Defendants willfully engaged in the conduct described herein, which they knew were deceptive in the course of retail business, trade and commerce, and had a deleterious impact on the public interest.

211. The NECC Related Defendants are liable to the Plaintiff for all statutory, direct and consequential damages, and fees and costs resulting from this breach, including multiple damages.

**COUNT VI**  
**PRODUCT LIABILITY CLAIMS**  
**(Against Saint Thomas Neurosurgical and Howell Allen Clinic)**

212. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

213. The MPA injected into Decedent's lumbar spine on August 27, 2012 and September 10, 2012 was compounded by NECC.

214. On December 21, 2012, NECC filed a voluntary petition pursuant to Chapter 11 of Title 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Massachusetts (Eastern Division) Case No. 12-19882-HJB.

215. Pursuant to 11 U.S.C. § 362(a)(1), certain actions against NECC are stayed following its bankruptcy petition.

216. Plaintiff could have commenced an action in this court seeking to recover on a claim and seeking a judgment against NECC before December 21, 2012.

217. Plaintiff's claims that arose before NECC's petition in bankruptcy are subject to the automatic stay provisions of 11 U.S.C. § 362(a)(1).

218. NECC has ceased operations.

219. NECC is unable to pay its debts as they fall due.

220. NECC is unable to pay its debts in the ordinary course of its business.

221. NECC's liabilities exceed its assets.

222. NECC is insolvent as declared by order dated July 24, 2013 in the Bankruptcy Proceeding.

223. Saint Thomas Neurosurgical procured the MPA injected into Decedent's lumbar spine from NECC.

224. NECC's product was defective and unreasonably dangerous when it left NECC's control because it was contaminated with lethal pathogens, and it was in substantially the same condition at the time that Saint Thomas Neurosurgical and Howell Allen Clinic injected it into Decedent's lumbar spine on August 27, 2012 and September 10, 2012.

225. Saint Thomas Neurosurgical and Howell Allen Clinic charged Decedent for ESIs administered to him.

226. Saint Thomas Neurosurgical and Howell Allen Clinic acted as a seller or distributor of MPA compounded by NECC when it sold and administered ESIs to patients, including Decedent.

227. Saint Thomas Neurosurgical and Howell Allen Clinic were engaged in the business of selling MPA compounded by NECC.

228. Accordingly, Saint Thomas Neurosurgical and Howell Allen Clinic are "sellers" as defined by Tenn. Code Ann. § 29-28-102(7).

229. Tenn. Code Ann. § 29-28-106(4) authorizes Plaintiff to prosecute product liability claims against Saint Thomas Neurosurgical and Howell Allen Clinic as the seller of the MPA injected into Decedent's lumbar spine because the compounder of the product, NECC, cannot be served with process in this state.

230. The MPA that Saint Thomas Neurosurgical and Howell Allen Clinic injected into Decedent's lumbar spine was unreasonably dangerous and defective at the time it was administered because it was contaminated with lethal pathogens.

231. Specifically, the MPA was in a defective condition and unreasonably dangerous at all relevant times because it was unsafe for normal or anticipated handling as defined by Tenn. Code Ann. § 29-28-102(2).

232. The MPA sold and distributed by Saint Thomas Neurosurgical and Howell Allen Clinic was neither merchantable nor fit for the purpose for which it was produced and sold. Accordingly, Saint Thomas Neurosurgical and Howell Allen Clinic breached its warranties, both express and implied, as stated in Tenn. Code Ann. §§ 47-2-313, 47-2-314 and 47-2-315, including its warranty of fitness for a particular purpose.

233. Saint Thomas Neurosurgical and Howell Allen Clinic are strictly liable for the injuries and losses caused by the unreasonably dangerous and defective steroids injected into Decedent's lumbar spine.

234. Out of an abundance of caution, neither this claim, nor any other claim or count asserted in this action, is meant to allege a claim arising under or otherwise covered by the Tennessee Medical Malpractice Act (the "TMMA"), T.C.A. § 29-26-101, *et. seq.*, against Defendants Saint Thomas West Hospital, Saint Thomas Network and Saint Thomas Health.

Plaintiff will amend this complaint to add, in the alternative, and out of an abundance of caution, claims under the TMMA at the appropriate time.

**COUNT VII**  
**AGENCY**  
**(Against Saint Thomas Neurosurgical and Howell Allen)**

235. All allegations above are incorporated herein by reference.

236. At all times relevant herein, NECC was acting as an agent of Defendants Saint Thomas Neurosurgical and Howell Allen in compounding drugs to be administered to the Decedent by said defendants.

237. A consensual fiduciary relationship arose when Defendants Saint Thomas Neurosurgical and Howell Allen contracted with NECC to procure compounded drugs from NECC for their patients, including Decedent.

238. Defendants Saint Thomas Neurosurgical and Howell Allen manifested assent for NECC to act as their agent, and on their behalf, when they contracted with NECC to procure compounded drugs from NECC to administer to their patients, including Decedent.

239. NECC consented to act as Defendants Saint Thomas Neurosurgical and Howell Allen's agent, and in their interest, when compounding, selling and delivering its compounded drugs to them, to be sold and administered to their patients, including the Decedent.

240. At all times relevant herein, NECC acted within the scope of its agency with Defendants Saint Thomas Neurosurgical and Howell Allen. As set forth herein, NECC acted negligently and or exhibited gross negligence in the compounding of NECC contaminated drugs.

241. Defendants Saint Thomas Neurosurgical and Howell Allen controlled the procurement of the drugs from NECC to be sold and administered to their patients, including the Decedent.



242. As a result, Defendants Saint Thomas Neurosurgical and Howell Allen are responsible for the negligence, gross negligence and wrongful conduct of NECC in compounding the contaminated drugs administered to Decedent.

**COUNT VIII**  
**CIVIL CONSPIRACY**  
**(Against Saint Thomas Neurosurgical, Dr. Allen and Howell Allen)**

243. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

244. Defendants, Saint Thomas Neurosurgical, Howell Allen, and Dr. Allen, acted in concert with NECC to accomplish the unlawful purpose of circumventing Massachusetts Board of Pharmacy patient safety requirements. Those Defendants accomplished that unlawful purpose via the unlawful means of using bogus patient lists to accompany orders of MPA. Those patient lists did not correspond with persons who actually received MPA, and the lists contained fictitious names such as "Mickey Mouse."

245. Defendants, Saint Thomas Neurosurgical, Howell Allen, and Dr. Allen, were aware of NECC's intent to use such patient lists in order to subvert Massachusetts Board of Pharmacy requirements.

246. The concerted action of NECC, Saint Thomas Neurosurgical, Howell Allen, and Dr. Allen, resulted in harm to Decedent and other patients who received NECC's MPA.

247. Defendants, Saint Thomas Neurosurgical, Howell Allen, and Dr. Allen are liable for the acts of their co-conspirator NECC.

**COUNT IX**  
**DUTY TO PREVENT FORESEEABLE HARM**  
**(Against Saint Thomas Neurosurgical, Dr. Allen and Howell Allen)**

248. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

249. Decedent played no role in selecting the supplier of the MPA that Defendant, Saint Thomas Neurosurgical, through its agents and employees, injected into his spine. Decedent relied exclusively upon Saint Thomas Neurosurgical, and its employees and agents, to make that selection.

250. Given the well-known dangers of bulk pharmacy compounding, Defendants, Saint Thomas Neurosurgical, Howell Allen, and Dr. Allen ignored grave risks of foreseeable harm when they permitted Saint Thomas Neurosurgical to purchase injectable steroids from NECC in bulk and without individual prescriptions.

251. Given the well-known dangers of bulk pharmacy compounding, Defendants, Saint Thomas Neurosurgical, Howell Allen, and Dr. Allen ignored grave risks of foreseeable harm when they permitted Saint Thomas Neurosurgical to conspire with NECC in the creation of false paper trails intended to hide NECC's wrongful and intentional conduct from regulators.

252. Defendants, Saint Thomas Neurosurgical, Howell Allen, and Dr. Allen stood in a special relationship with Decedent. By virtue of that special relationship, Defendants, Saint Thomas Neurosurgical, Howell Allen, and Dr. Allen owed a duty to protect their patients, including Decedent, from foreseeable harm caused by NECC's intentional conduct. NECC engaged in numerous instances of intentional misconduct. That intentional misconduct included but is not limited to: (a) mass producing compounded medications and selling them in bulk in circumvention of the FDA system of regulating drug manufactures; (b) providing false information to government regulators; (c) mass producing compounded medications and shipping those medications to Tennessee without patient specific prescriptions in violation of Massachusetts Board of Pharmacy Rules and Tenn. Code Ann. § 63-10-204(4); (d) enlisting the aid of its customers (including Saint Thomas Neurosurgical) in creating false paper trails

designed to hide its misconduct from government regulators; and (e) mass producing purportedly sterile injectable drugs under filthy conditions in violation of regulations promulgated by the Massachusetts Board of Registration in Pharmacy and found at 24 7 CMR 6.02(1).

253. Defendants, Saint Thomas Neurosurgical, Howell Allen, and Dr. Allen breached their duty to their patients, including Decedent, by failing to protect them from the foreseeable harm caused by NECC's intentional conduct.

254. As a direct and proximate result of Defendants, Saint Thomas Neurosurgical, Howell Allen, and Dr. Allen breach of their duties, Decedent suffered physical injuries and death.

255. Because Defendants, Saint Thomas Neurosurgical, Howell Allen, and Dr. Allen owed Decedent a duty to protect him from NECC's conduct, their fault cannot be reduced by any fault attributable to NECC. Accordingly, Defendants, Saint Thomas Neurosurgical, Howell Allen, and Dr. Allen are jointly and severally liable for all harm caused by NECC's conduct.

**COUNT X**  
**OTHER CLAIMS AGAINST SAINT THOMAS NEUROSURGICAL**

256. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

257. Saint Thomas Neurosurgical's decision to select NECC as its supplier of purportedly sterile injectable steroids was negligent.

258. Saint Thomas Neurosurgical knew or should have known that NECC was not a safe and reputable supplier of injectable steroids such as MPA.

259. Saint Thomas Neurosurgical acting through its agents, employees, and representatives negligently and recklessly purchased contaminated MPA from NECC.

260. Saint Thomas Neurosurgical failed to conduct appropriate due diligence regarding NECC. Had they done so, any reasonable purchaser would have declined to purchase from NECC.

261. Saint Thomas Neurosurgical, acting through its physicians, nurses, managers, agents, and employees, was negligent in its care and treatment of Decedent. Such care and treatment fell below the recognized standard of acceptable professional practice for pain management and drug procurement practices in this or similar communities and was a proximate cause of Decedent's injuries and damages. Specifically, Saint Thomas Neurosurgical was negligent and rendered substandard care in the following respects:

- a. procured injectable steroids from NECC, for the purpose of injecting those medications into the spines of patients for profit, without conducting adequate due diligence regarding whether NECC was a reputable and safe supplier of sterile injectable compounds;
- b. failed to visit NECC's facilities before procuring spinal injection medicines from that company;
- c. failed to investigate and exercise sufficient due diligence before administering injectable steroids procured from NECC, including its failure to investigate or inquire concerning NECC's compounding practices;
- d. failed to determine whether NECC had a history of recalling compounded medications before procuring spinal injection medicines from that company;
- e. failed to investigate NECC's regulatory history with the FDA and/or the Massachusetts Board of Registration in Pharmacy before procuring spinal injection medicines from that company;
- f. failed to determine whether NECC had a history of product liability suits before procuring spinal injection medicines from that company;
- g. failed to keep abreast of the dangers of sterile compounding;
- h. purchased compounded injectable steroids in bulk from NECC

without using patient-specific individual prescriptions;

- i. failed to adequately supervise and train the physicians, nurses, agents and employees who ordered MPA from NECC;
- j. failed to follow its own formulary that would have prevented the use of MPA compounded by NECC in ESIs;
- k. failed to implement policies and procedures that would prevent the procurement of purportedly sterile injectable medications from an out-of-state compounding pharmacy with deplorable sterility procedures, a checkered regulatory past, product recall problems, and a history of product liability suits;
- l. injected steroids into Decedent's lumbar spine without taking reasonable steps to ensure that those medicines were from a reputable supplier and were not contaminated with lethal pathogens;
- m. approved, facilitated or permitted the purchase of MPA from NECC because it was less expensive than safer alternatives;
- n. failed to promptly notify Decedent that he was injected with potentially contaminated steroids and failed to recommend that he receive prompt treatment for his exposure to potential fungal infection;
- o. purchased compounded injectable steroids in bulk from NECC without using patient specific individual prescriptions; and
- p. submitted lists of patients' names to NECC when ordering MPA even though such lists did not correspond with patients who actually received MPA.

262. As a direct and proximate result of the negligent acts and omissions described above, Decedent and Plaintiff suffered injuries and damages that would not have otherwise occurred.

263. The physicians, nurses, agents, employees and representatives who decided to procure MPA from NECC and who injected that steroid into Decedent's lumbar spine were employees or agents of Saint Thomas Neurosurgical, and they were acting within the course and scope of their employment or agency. Accordingly, Saint Thomas Neurosurgical is

liable for the consequences of said person's or persons' conduct pursuant to the doctrine of *respondeat superior*.

**COUNT XI  
CLAIMS AGAINST VAUGHAN A. ALLEN, M.D.**

264. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further alleges:

265. Dr. Allen was negligent in his selection of NECC as a supplier of MPA to Saint Thomas Neurosurgical.

266. Dr. Allen knew or should have known that NECC was not a safe and reputable supplier of injectable steroids such as MPA.

267. Dr. Allen failed to conduct appropriate due diligence regarding NECC. Had they done so, any reasonable purchaser would have declined to purchase from NECC.

268. Dr. Allen's decision to purchase MPA in bulk from NECC was based solely on price.

269. In making the decision to purchase compounded MPA from NECC, Dr. Allen failed to follow the medication formulary adopted by Saint Thomas Neurosurgical.

270. Dr. Allen was negligent in his care and treatment of Decedent. Such care and treatment fell below the recognized standard of acceptable professional practice for physicians and registered nurses in similar circumstances in this or similar communities and was a proximate cause of Mr. Patel's injuries and damages. Specifically, Dr. Allen was negligent and rendered substandard care in the following respects:

- a. procured injectable steroids from NECC, for the purpose of injecting those medications into the spines of patients for profit, without conducting adequate due diligence regarding whether NECC was a reputable and safe supplier of sterile injectable compounds;

- b. failed to visit NECC's facilities before procuring spinal injection medicines from that company;
- c. failed to investigate and exercise sufficient due diligence before administering injectable steroids procured from NECC, including its failure to investigate or inquire concerning NECC's compounding practices;
- d. failed to determine whether NECC had a history of recalling compounded medications before procuring spinal injection medicines from that company;
- e. failed to investigate NECC's regulatory history with the FDA and/or the Massachusetts Board of Registration in Pharmacy before procuring spinal injection medicines from that company;
- f. failed to determine whether NECC had a history of product liability suits before procuring spinal injection medicines from that company;
- g. failed to keep abreast of the dangers of sterile compounding;
- h. purchased compounded injectable steroids in bulk from NECC without using patient-specific individual prescriptions;
- i. failed to adequately supervise and train the physicians, nurses, agents and employees who ordered MPA from NECC;
- j. failed to follow its own formulary that would have prevented the use of MPA compounded by NECC in ESIs;
- k. failed to implement policies and procedures that would prevent the procurement of purportedly sterile injectable medications from an out-of-state compounding pharmacy with deplorable sterility procedures, a checkered regulatory past, product recall problems, and a history of product liability suits;
- l. injected steroids into Decedent's lumbar spine without taking reasonable steps to ensure that those medicines were from a reputable supplier and were not contaminated with lethal pathogens;
- m. approved, facilitated or permitted the purchase of MPA from NECC because it was less expensive than safer alternatives;
- n. failed to promptly notify Decedent that he was injected with potentially contaminated steroids and failed to recommend that he receive prompt treatment for his exposure to potential fungal

infection;

- o. purchased compounded injectable steroids in bulk from NECC without using patient specific individual prescriptions; and
- p. submitted lists of patients' names to NECC when ordering MPA even though such lists did not correspond with patients who actually received MPA.

271. As a direct and proximate result of the negligent acts and omissions described above, Decedent and Plaintiff suffered injuries and damages that would not have otherwise occurred.

## **COUNT XII WRONGFUL DEATH CLAIM**

272. Plaintiff incorporates by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further allege:

273. Plaintiff, individually, and for the benefit of all wrongful death beneficiaries, sues pursuant to the Wrongful Death Act and seeks the full value of Decedent Gokulbhai Maganbhai Patel's life.

274. The conduct described herein was caused by Defendants' and their agents' and servants' wrongful acts, neglect, carelessness, unskillfulness, and default.

275. As a direct and proximate result of Defendants' conduct and omissions described herein, the product Decedent received caused the injuries and damages as described with particularity herein.

276. Plaintiff seeks damages for the fair monetary value of the Decedent's injuries, physical conscious pain and suffering and mental and emotional anguish, the value of the Decedent to each of the beneficiaries of the estate, including but not limited to compensation for the loss of the reasonably expected net income, services, protection, care, assistance, society,



companionship, comfort, guidance, counsel and advice of the Decedent. Plaintiff seeks recovery for the reasonable medical and funeral expenses of the Decedent.

277. Defendants' willful, wanton, and reckless acts and omission and gross negligence caused Decedent's death and warrant the estate recovering punitive damages.

**PLAINTIFF'S COMPLIANCE WITH  
TENN. CODE ANN. §§ 29-26-121 AND 29-26-122<sup>1</sup>**

278. Plaintiff complied with the notice requirements of Tenn. Code Ann. §§ 29-26-121(a) and provided the required documentation specified in § 29-26-121(a)(2) to appropriate defendants more than 60 days before the filing of the Complaint.

279. Plaintiff has demonstrated his compliance with the provisions of Tenn. Code Ann. §§ 29-26-121(a)(1), 29-26-121(a)(2), 29-26-121(a)(3)(B), 29-26-121(a)(4) and 29-26-121(b) as evidenced by the Affidavit included as Exhibit A (which is incorporated herein by reference and hereinafter referred to as the "Affidavit"), which establishes compliance with Tenn. Code Ann. § 29-26-121 and includes as attachments copies of the Certificates of Mailing from the United States Postal Service stamped with the date of mailing along with copies of the notices sent to the healthcare defendants.

280. With regard to Defendant Saint Thomas Neurosurgical, Plaintiff complied with the requirements of Tenn. Code Ann. § 29-26-121(a) by sending notice of the claim via certified mail, return receipt requested, to Saint Thomas Neurosurgical at both the address for its agent for service of process and the provider's current business address. As set forth in the Affidavit, the notices were sent to Saint Thomas Neurosurgical on August 23, 2013, by certified mail, return

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<sup>1</sup> Plaintiff has provided Notice under Tenn. Code Ann. § 29-26-121(a) to Defendants Saint Thomas West Hospital, Saint Thomas Network and Saint Thomas Health, however, 60 days has not yet passed. Therefore, Plaintiff will amend to add counts against Defendants Saint Thomas West Hospital, Saint Thomas Network and Saint Thomas Health once the required timeframe has passed. Plaintiff files this action against said defendants to preserve his products liability action.

receipt requested. A copy of the notice and enclosures along with the certificates of mailing from the United States Postal Service stamped with the date of mailing are attached to the Affidavit.

281. With regard to Defendant Howell Allen Clinic, Plaintiff complied with the requirements of Tenn. Code Ann. § 29-26-121(a) by sending notice of the claim via certified mail, return receipt requested, to Howell Allen Clinic's registered agent for service of process. Howell Allen Clinic's current business address is the same as the address of its registered agent. As set forth in the Affidavit, the notice was sent to Howell Allen Clinic on August 23, 2013, by certified mail, return receipt requested. A copy of the notice and enclosures along with the certificate of mailing from the United States Postal Service stamped with the date of mailing are attached to the Affidavit.

282. With regard to Defendant Dr. Allen, Plaintiff complied with the requirements of Tenn. Code Ann. § 29-26-121(a) by sending notice of the claim via certified mail, return receipt requested, to Dr. Allen's current business address. As set forth in the Affidavit, the notice was sent to Howell Allen Clinic on August 23, 2013, by certified mail, return receipt requested. A copy of the notice and enclosures along with the certificate of mailing from the United States Postal Service stamped with the date of mailing are attached to the Affidavit.

283. The requirements of Tenn. Code Ann. § 29-26-121 as to Defendants Saint Thomas Neurosurgical, Howell Allen Clinic and Dr. Allen have been satisfied.

284. Pursuant to Tenn. Code Ann. § 29-26-122(a), a Certificate of Good Faith signed by the undersigned counsel is included as Exhibit B and incorporated herein by reference.

### **DAMAGES**

285. As a direct and proximate result of the Defendants' wrongful conduct as described above, Decedent has suffered physical injuries and death, physical and mental pain and suffering, mental anguish, loss of enjoyment of life and loss of earning capacity.